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Calibration Specification for Medical Pressure Pulse Lithotripsy Machines

医用体外压力脉冲碎石机校准规范

(English Translation)

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Appendix A Internal Page Format of Calibration Certificate for Medical Extracorporeal Pressure Pulse Lithotripter (7)

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Introduction

This specification is based on the rules and format given in JJF 1071-2010 "Rules for Compiling National Measurement and Calibration Specifications" prepared by.

The standard reference GB/T 16407-2006 "Acoustic medical external pressure pulse lithotripter sound field characteristics and measurement Volume ", GB 9706.22-2003" Medical Electrical Equipment Part 2. Safety Requirements for In Vitro Lithotripsy Equipment " Requirement and other relevant domestic and foreign standards are formulated.

This specification is the first release.

Calibration specification for medical extracorporeal pressure pulse lithotripter

1 Scope

This specification applies to the calibration of electromagnetic medical external pressure pulse lithotripters.

Hydroelectric and piezoelectric medical extracorporeal pressure pulse lithotripters can be implemented with reference to this specification.

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2 Reference documents this specification refers to the following documents.

JJF 1001-2011 General Measurement Terms and Definitions JJF 1034-2005 Acoustic measurement terms and definitions GB 3102.7-1993 Acoustic quantities and units GB 9706.1-2007 Medical electrical equipment Part 1. General requirements for safety GB 9706.22-2003 Medical electrical equipment Part 2. Particular requirements for the safety of in vitro lithotripsy equipment GB/T 16407-2006 Acoustic medical external pressure pulse lithotripter sound field characteristics and measurement YY0001-2008 Technical requirements for in vitro lithotripsy equipment for dated reference documents, only the dated version applies to this specification; for those without date references the latest version (including all amendments) is applicable to this specification.

3 Terms and units of measurement

3.1 Lithotripsy

Crushing or breaking of human stones.

3.2 Pressure pulse Sound pressure pulses generated by medical lithotripters.

3.3 focus

In the pressure pulse sound field, the position of the maximum positive peak sound pressure.

3.4 Focal volume

The volume of the space enclosed by the interface 6dB lower than the maximum positive peak sound pressure (0dB) around the focal point.

3.5 Maximum focal width in the (x, y) plane containing the focal point, the maximum sound pressure line around the focal point is 6dB lower than the maximum positive peak sound pressure.

Large width.

3.6 Width of positive sound pressure pulse widthofpressurepulse Before and after the peak value of the sound pressure pulse, the sound pressure value is equal to the time difference between the two instantaneous sound pressures of 50% of the peak value of the pulse, in units for seconds (s).

3.7 Rise time of pressure pulse the time from 10% of the positive peak of the pressure pulse to 90%, in seconds (s).

3.8 Pressure pulse generator generatorofpressurepulse

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